REMARKS

An Office Action was sent from the U.S. Patent and Trademark Office on August 4, 2003, carrying a response due date of November 4, 2003. As such, Applicants response is timely.

Claim Rejections under 35 U.S.C. §112 first paragraph

The Examiner has rejected Claims 4 and 5 under 35 U.S.C. §112 first paragraph for failing to provide an adequate written description of the invention and failing to provide an enabling disclosure because the specification does not provide evidence that the claimed biological materials are (1) known and readily available to the public; (2) reproducible from a written description or (3) deposited.

Claims 4 and 5 of the current invention are drawn to monoclonal antibodies 13G3 and 4E10. These antibodies are produced from hybridoma cell lines. The starting material used to make the hybridoma cell lines is type A feline blood. Type A feline blood is known and readily available to the public. The steps of making the hybridoma cell lines, which produce the monoclonal antibodies of interest in the invention are disclosed in the current application. Further, to those people skilled in the monoclonal antibody art, the method of developing hybridoma cell lines, which make 13G3 and 4E10, from feline blood would be considered well known. (See Paragraphs 2 and 3 of the Declaration of Gordon Andrews). The 13G3 and 4E10 antibodies are murine IgM antibodies. The monoclonal antibody 4E10 recognizes the A antigen $(NeuGc)_2G_{D3}$. The 13G3 antibody recognizes the A antigen $(NeuGc)G_{T3}$ and related antigens. It

is disclosed in the application that these antibodies can be used in combination to type feline blood.

The current application, particularly in Example 1, discloses the procedure one skilled in the art would follow in order to develop the hybridoma cell lines which produce the monoclonal antibodies of interest. The monoclonal antibodies can be produced from type A feline blood by someone skilled in the monoclonal antibody art, without undue experimentation. (See Paragraphs 2 and 3 of the Declaration of Gordon Andrews). The current application, in particular at Example 2, discloses how the monoclonal antibodies are then tested to determine which ones bind to A antigen $(NeuGc)_2G_{D3}$ and which antibodies bind to A antigen $(NeuGc)G_{T3}$. Once the hybridoma cell lines are created which produce the monoclonal antibodies, routine screening, which does not amount to undue experimentation, is required to determine which hybridoma cell lines are producing the antibodies of interest. (See Paragraphs 2 and 3 of the Declaration of Gordon Andrews).

According to §2404.02 of the Manual of Patent Examining Procedures (MPEP) a deposit is not necessary even though specific biological materials are required to practice the invention, if those biological materials can be made or isolated without undue experimentation. Thus, when the required biological materials can be obtained from publicly available material with only routine experimentation and a reliable screening test, a deposit is not necessary. The current application meets these requirements.

The U.S. Court of Appeals for the Federal Circuit (the CAFC) has determined that a patent does not fail to meet the enablement requirement of 35 U.S.C. §112 by requiring "undue experimentation," even though production of monoclonal antibodies necessary to practice the invention first requires the production and screening of numerous hybridomas since those skilled

in the art are prepared to screen negative hybridomas in order to find those that produce the desired antibodies. In re Wands 8 USPQ2d 1400, 858 F2d 731 (Fed.Cir. 1988). The Wands case, dealt with the Patent and Trademark Office (PTO) rejecting an application under 35 U.S.C. §112, first paragraph as not enabling one skilled in the art to make the monoclonal antibodies needed to practice the claimed invention. The CAFC reversed the PTO Board of Patent Appeals and Interferences and found that the Wands application would enable one skilled in the monoclonal antibody art to practice the invention without undue experimentation. Id. at 1407. The CAFC determined that a deposit of high affinity monoclonal antibodies of the IgM isotope were not required to find enablement of the patent application because "the monoclonal antibodies needed to perform the immunoassays can be made from readily available starting materials using methods that are well known in the monoclonal antibody art." Id. at 1404.

In Wands, as in the current invention, the starting materials were routinely available to the public. Further, the PTO conceded that methods used to prepare hybridomas and screen them for IgM antibodies, were either well know in the monoclonal antibody art or adequately disclosed in the patent and application. Id. at 1405. Thus, the CAFC found that methods for obtaining and screening monoclonal antibodies were well known in 1980 and the only issue was whether it would require undue experimentation to produce high affinity IgM monoclonal antibodies. Id. The CAFC stated that enablement "is not precluded by the necessity for some experimentation such as routine screening." However, experimentation needed to practice the invention must not be "undue experimentation." According to the CAFC the key word is "undue" and not "experimentation". As long as the experimentation required to perform the invention is not undue the description should be considered enabling. Id.

According to the CAFC, a "determination of what constitutes undue experimentation in a given case requires the application of a standard of reasonableness having due regard for the nature of the invention and the state of the art." Id. Thus, the test is "not merely quantitative since a considerable amount of experimentation could be permissible if it is routine experimentation or if the specification provides a reasonable amount of guidance with respect to the direction of which the experimentation should proceed." Id. The CAFC proceeded to list factors, which should be considered in determining whether a disclosure requires undue experimentation. Factors include "(1) the quantity of experimentation necessary; (2) the amount of direction or guidance presented; (3) the presence or absence of working examples; (4) the nature of the invention; (5) the state of the prior art; (6) the relative skill of those in the art; (7) the predictability or unpredictability of the art; and, (8) the breath of the claims." Id.

In the present case, the application and in particular, Examples 1 and 2 set forth instructions as to how to replicate the current invention and show working examples of such. The examples start by using type A feline blood, which is readily available to the public. The instructions given throughout the application, and in particular in Examples 1 and 2, along with the state of the prior art would allow someone skilled in the monoclonal antibody art to develop hybridoma cell lines which produce the monoclonal antibodies of interest. Once the monoclonal antibodies were produced, routine screening methods can be used to determine which hybridoma cell lines are producing the monoclonal antibodies of interest, specifically monoclonal antibody 13G3 and monoclonal antibody 4E10.

As the CAFC noted in the Wands case, the making of hybridoma cell lines and the screening techniques for determining which monoclonal antibodies produced by the hybridoma cell lines are well known in the field of monoclonal antibody art. While some experimentation

may be required to determine which of the monoclonal antibodies produced by the hybridoma cell lines are the 13G3 or 4E10 monoclonal antibodies, such screening would be considered routine for someone skilled in the art of monoclonal antibody production. (See Paragraphs 2 and 3 of the Declaration of Gordon Andrews). Thus, Applicant believes that the use of type A feline blood which is readily available to the public along with the instructions given in the application and the current state of the art at the time the application was filed would clearly allow someone skilled in the art to reproduce the results and precludes the need for a biological deposit in the current application.

Claim Rejections under 35 U.S.C. §112 second paragraph

The Examiner has rejected Claim 11 under 35 U.S.C. Section 112, second paragraph for being indefinite for failing to particularly point out and distinctly claim the subject matter of the invention. Applicants have amended Claim 11 to depend from Claim 10. This Amendment distinctly claims the subject matter of the invention.

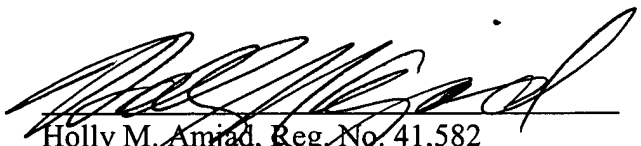
Applicants believe the amendment to Claim 11 more clearly defines the invention, overcomes the Examiner's rejection and places the application in proper form for allowance.

It is asserted that the amendment to the claims has placed the application in proper form for allowance. As such, it is respectfully requested that the present invention be allowed.

If the Examiner has any suggested changes, which would place the present application in condition for allowance, please contact Applicants' attorney at the number listed below.

Respectfully submitted,

POLSINELLI SHALTON & WELTE, P.C.



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